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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVIDE R. GRASSETTI and CAMILLO MORO

Appeal 2010-008088
Application 10/044,463
Technology Center 1600

Before DEMETRA J. MILLS, FRANCISCO C. PRATS, and STEPHEN WALSH, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

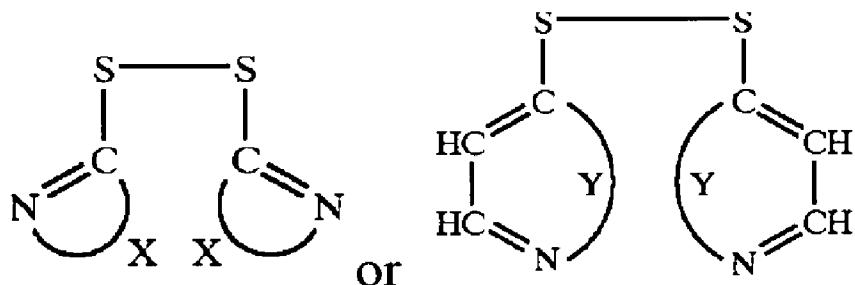
DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The following claim is representative and reads as follows:

1. A method for modulating an immune response comprising:
identifying an individual in need of immune response modulation;
administering to the individual in need of immune response modulation an effective amount of a thione-forming disulfide comprising



wherein X and Y represent atoms necessary to form a five-membered or six-membered substituted or unsubstituted heterocyclic ring;
wherein the immune response is selected from the group consisting of:
a cellular response, a humoral response and an innate immune response; and,
wherein the individual is other than an individual infected with a
retrovirus;
thereby modulating the immune response.

Cited References

The Examiner relies on following prior art references:

Grassetti US 4,378,364 Mar. 29, 1983
Oliver et al., T Cell Immune Response to Cancer in Humans and Its Relevance for Immunodiagnosis and Therapy, (13) A New Look at Tumour Immunology, 173-204 (1991).
Tagawa, Cytokine Therapy for Cancer, (6) Current Pharmaceutical Design, 681-699 (2000).

Grounds of Rejection

1. Claims 1-2, 5-6, 10-12 and 20-24 were rejected under 35 U.S.C. §§ 102(b) and 103(a) as anticipated and as obvious over Grassetti as evidenced by Oliver and Tagawa.

FINDINGS OF FACT

The Examiner's fact findings are set forth in the Answer at pages 3-7.

Discussion

ISSUE

The Examiner concludes that Grassetti teaches each element claimed. Appellants argue that the Examiner has failed to present a *prima facie* case of anticipation and that the cited prior art does not teach the limitations of “1) identifying an individual in need of immune response modulation, and 2) administering a thione-forming disulfide... to an individual in need of immune response modulation.” (App. Br. 6.)

The issue is: Does the cited prior art support the Examiner's rejection of the claims for anticipation.

PRINCIPLES OF LAW

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that

burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citations omitted). In order to determine whether a *prima facie* case of obviousness has been established, we consider the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present.

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

“[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.” *In re Baxter-Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

ANALYSIS

We agree with the Examiner’s fact finding, statement of the rejection and responses to Appellant’s arguments as set forth in the Answer. We provide the following additional comment.

Appellants argue that the Examiner has failed to present a *prima facie* case of anticipation and that the cited prior art does not teach the limitations of “1) identifying an individual in need of immune response modulation, and 2) administering a thione-forming disulfide... to an individual in need of immune response modulation.” (App. Br. 6.)

Grassetti teaches administering the same thione-forming compound as claimed by Appellants to a cancer patient who has had surgery. (Ans. 4.)

Oliver evidences that cancer patients who have had surgery have suppressed immune responses. (Ans. 4-5.) Grassetti further discloses that cancer patients who have had surgery are treated with the thione-forming compound until their natural defenses have destroyed the remaining circulating cancer cells. (Ans. 4.) Thus, it is reasonably concluded by one of ordinary skill in the art that the cancer patient who has had surgery is treated until the suppressed immune responses have been modulated such that the natural defenses are again functional. Therefore, we are not persuaded that Grassetti does not teach an individual in need of immune response modulation.

Oliver establishes that a cancer patient who has had surgery has a suppressed immune system and is in need of immune response modulation. Therefore, Grassetti, by its teaching to administer a thione-forming disulfide to a cancer surgery patient, teaches administering a thione-forming disulfide to an individual in need of immune response modulation.

We conclude the Examiner has presented a *prima facie* case of anticipation. “[W]hen a *prima facie* case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability.” *In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002).

Appellants argue that the statement in Grassetti that the patient is treated until natural defenses have destroyed the remaining circulating cancer cells means that the patient’s “natural (unmodulated) defenses are adequate to destroy the cancer cells.” (App. Br. 14.) However, this statement by Appellants is attorney argument and Appellants have not presented any evidence to support that one of ordinary skill in the art would understand Grassetti discloses that the natural defenses have been

unmodified or that a cancer patient who has had surgery does not have a suppressed immune system.

Appellants argue that not all patients receiving chemotherapy are necessarily in need of immune response modulation and Grassetti does not identify any individual in need of immune response modulation. (See App. Br. 9.) We are not persuaded. As discussed herein, the evidence of record shows that a cancer patient having had surgery as in Grassetti is immune suppressed and in need of immune response modulation.

With respect to the obviousness rejection we find that “anticipation is the epitome of obviousness.” In re McDaniel, 293 F.3d 1379, 1385 (Fed. Cir. 2002). Moreover, Appellants have not presented sufficient argument or evidence to rebut the Examiner’s prima facie case of obviousness.

The anticipation and obviousness rejections are affirmed.

CONCLUSION OF LAW

The cited references support the Examiner’s anticipation and obviousness rejections.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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